



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

AUG 19 2009

Re: Banzel  
Docket No.: FDA-2009-E-0056

The Honorable Jon Dudas  
Undersecretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,740,669, filed by Novartis AG, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Banzel (rufinamide), the human drug product claimed by the patent.

The total length of the regulatory review period for Banzel (rufinamide) is 6,595 days. Of this time, 5,501 days occurred during the testing phase and 1,094 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 27, 1990.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 27, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: November 17, 2005.

FDA has verified the applicant's claim that the new drug application (NDA) 21-911 was submitted on November 17, 2005.

3. The date the application was approved: November 14, 2008.

FDA has verified the applicant's claim that NDA 21-911 was approved on November 14, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, reading "Jane A. Axelrad". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Jason M. Okun  
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